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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/723,043

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Stephen D. Pacetti

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,043	Applicant(s) PACETTI, STEPHEN D.	
	Examiner Eric E. Silverman, PhD	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28, 29 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 2/28/2008 has been received. Claims 28, 29 and 36 are pending.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 28, 29, and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by US 6,527,938 to Bales et al.

1 Claim interpretation

Claim 28 reads on a method of coating an implantable device by applying a composition on the device, wherein the applied composition includes a first block copolymer (the elected first block copolymer is SIBS) and a material selected from (1) a biobeneficial polymer capable of forming a conjugate with the first block copolymer, (2) a second block copolymer or (3) a combination thereof. The claim recites specific limitations of the second block copolymer. However, because the claim does not actually require a second block copolymer, these limitations are understood to be in force only when the second block copolymer is present. In embodiments of the claim wherein the material is a biobeneficial polymer capable of forming a conjugate with the first block copolymer only, the limitations on the second block copolymer do not apply. Also, note that the term "capable of forming a conjugate with the first block copolymer" does not equate to existing in the form of a conjugate with the first block copolymer. Any biobeneficial polymer that could form a conjugate with the first (SIBS) block copolymer meets this requirement.

Claim 29 requires that an active agent also be present in the coating, and claim 36 requires that the implant be a stent.

2 Reason for the holding of anticipation

Bates teaches a method of coating a titanium stent by applying a bio-compatible polymer, such as SIBS, and a bio-resorbably polymer, such as polyglycolic acid, and an active agent. Col. 2, lines 22 – 33. Glycolic acid is a “biobeneficial polymer capable of forming a conjugate with the first [SIBS] block copolymer,” as claimed. For example, polyglycolic acid could be conjugated to SIBS by standard techniques of synthetic organic chemistry.

Claims 28, 29, and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by US 6,484,097 to Pinchuck et al.

The interpretation of these claims was discussed above.

Pinchuck discloses a stent coated with SIBS and methods of making the same. Figure 1 and descriptions thereof, examples. Active agents may be included in the coating. Claim 14. Among the active agents are DNA. Claim 30. DNA is a copolymer containing a biobeneficial component. DNA also contains thymine, which is a component that is insoluble (“very slightly soluble”) in water. See Thymine MSDS as evidence of thymine’s solubility.

Response to Arguments

Applicants’ arguments have been fully considered, but are not persuasive. Applicants’ argued that the art of record does not teach the material selected from (1) a biobeneficial polymer capable of forming a conjugate with the first block copolymer, (2)

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a second block copolymer or (3) a combination thereof, as now recited by claim 28. As discussed above, the art teaches this material.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD

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